AF 3731

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Chandru Chandrasekaran

Appln No.: 10/075,914

Filed: 02/14/2002

Title: METAL REINFORCED BIODEGRADABLE INTRALUMINAL STENTS

Art Unit: 3731

Examiner: Sarah K. Webb

Confirmation No.: 1739

Docket No.: 01-462

Mail Stop Appeal Brief-Patents
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF UNDER 37 CFR §1.193(b)

Dear Sir:

This is a reply pursuant to 37 C.F.R. §1.193(b) in response to the Examiner's Answer mailed on August 10, 2005, in the appeal from the Examiner's decision dated September 24, 2004, finally rejecting Claims 1-27 of the above-referenced patent application.

This Reply Brief is filed within two months of the Examiner's Answer mailed August 10, 2005.

Attached to this Brief as ***Appendix A*** is a copy of all the claims involved in this appeal as required under 37 C.F.R. §1.192(c)(9).

I. *Real Party In Interest.*

The statement contained in the Appeal Brief identifying the real party in interest is incorporated herein by this reference.

II. *Related Appeals and Interferences.*

The statement contained in the Appeal Brief indicating that there are no related appeals or interferences for this application or any related co-pending applications (despite the Examiner's statement to the contrary) is incorporated herein by reference.

III. *Status of the Claims*

The statement contained in the Appeal Brief indicating the status of the claims is incorporated herein by this reference.

IV. *Status of Amendments*

As indicated in the Appeal Brief and confirmed in the Examiner's Answer, the Appellants did not amend any of the claims subsequent to the final rejection.

V. *Summary of the Invention*

The summary of the invention contained in the Appeal Brief is incorporated herein by this reference.

VI. *Issues*

Further to the withdrawal of the claim rejection under 35 U.S.C. §112 in the Examiner's Answer, the issues are as follows:

1. Whether the invention of Claims 1-10, 13, 15, 18, 20-22, 25 and 27 is patentable in light of the rejection under 35 USC 102 (b) as being unpatentable over US Patent 5,824,049 to Ragheb et al. (Ragheb)

2. Whether the invention of Claims 1, 5-10 and 12-14 is patentable in light of the rejection under 35 USC 102(b) as being unpatentable over US Patent 5,725,567 to Wolff et al. (Wolff).

3. Whether the invention of dependent Claims 2 and 11 is patentable in light of the rejection under 35 USC 103(a) as being unpatentable over Wolff in view of US Patent 5,630,840 to Mayer.

4. Whether the invention of Claims 14, 16, 17, 19, 23, 24 and 26 is patentable in light of the rejection under 35 USC 103(a) as being unpatentable over Ragheb in view of Wolff.

VII. *Grouping of Claims*

Appellant inadvertently omitted a statement for this section in the principal brief, notwithstanding the Examiner's remarks to the contrary. As is apparent in the principal brief, no claims were argued separately within each rejection.

VIII. *Argument*

After due consideration of the Examiner's answer, Appellant believes it is necessary to respond to errors of fact and law that emphasize the erroneous nature of the Examiner's rejections. The legal precedents applicable to the issues in this appeal, most particularly the issue of "inherency," are set forth in the principal brief, except for the following: *Ex parte Rubin*, 5 U.S.P.Q.2d 1461(BPAI 1987).

In the discussion of the prior art at paragraph [0006] of the specification, Appellant citing two prior U.S. patents issued prior to Appellant's invention, stated that it had been believed that a metallic stent, with or without a polymer coating, required sufficient strength in the metallic portion to maintain patency of a lumen "upon implantation." Those patents issued around or significantly after the time the reference patents relied on by the Examiner issued.

Nothing in the references of record or elsewhere in the prior art discloses the crucial concept of the claimed invention. Lack of a teaching of "concept" was discussed in the principal brief. No published authority was cited. It if should be considered to be necessary, Appellant would cite *Ex parte Rubin*, 5 U.S.P.Q.2d 1461(BPAI 1987). It is the concept reflected particularly in the final paragraph of independent claim 1 that gives rise to the important advantages set forth at pages 3 to 4 of the original brief.

Despite the foregoing fact, the Examiner has speculated, without evidence or reasonable explanation, that the stents of Ragheb and Wolff met the terms of the appealed claims. The error involved in concluding anticipation or obviousness based on sheer speculation is discussed at length in the principal brief.

In the Examiner's answer (page 7), the Examiner has attempted to explain her conclusion of inherency by speculating that the prior art stents *could* somehow be improperly implanted in an inappropriately large lumen or that restenosis or similar phenomena eventually *could* occur such that no stent can maintain patency of a lumen, the latter of which is a new argument. Restenosis is discussed in Ragheb (see, e.g., Background of The Invention and column 8, lines 6-10) and Wolff (see, e.g., Abstract, Background of The Invention and column 4, lines 34 et seq.). Both references utilize pharmaceutical agents to prevent restenosis. Appellant's specification (e.g., paragraph [0031]) discusses restenosis and the use of agents to prevent or delay the occurrence of restenosis over time (e.g., paragraph [0049]).

However, the appealed claims require that the metallic component of the stent be insufficient to maintain patency of the lumen "upon implantation," not after the passage of some indeterminate time. Thus the new argument set forth by the Examiner is unconvincing

of lack of error in the rejections of record, as discussed in the principal brief, including the fact that a holding of inherency must flow as a necessary conclusion from the prior art, not simply a possible one.

Appellant's assertions that the metallic stents disclosed in the references are sufficient in and of themselves to maintain patency of a lumen upon insertion and that they do not meet the terms of the appealed claims have not been rebutted in any meaningful fashion.

A stent as claimed, which comprise a metallic reinforcing component that provides structural reinforcement for the stent but which is insufficient, in the absence of the biodegradable polymeric material covering at least a portion of the metallic reinforcing component, to provide a stent capable of maintaining patency of a lumen upon implantation of the stent into the lumen, is novel and unobvious in view of the prior art.

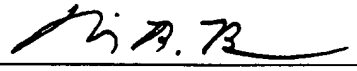
IX. *Conclusion*

For the foregoing reasons, in addition to those set forth in the principal brief, it is respectfully submitted that reversal of the examiner's rejection of all claims is in order.

X. *Fees*

The Commissioner is hereby authorized to charge any fees due and owing in this matter to the undersigned attorney's PTO Deposit Account No. 50-1047.

Respectfully submitted,



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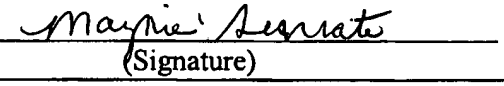
Marjorie Scariati

(Printed Name of Person Mailing Correspondence)



(Signature)

XI. APPENDIX A

The claims involved in the appeal, Claims 1-27, are reproduced below.

1. (Original) An intraluminal stent comprising:

a metallic reinforcing component; and

a biodegradable polymeric material covering at least a portion of the metallic reinforcing component;

the metallic reinforcing component providing structural reinforcement for the stent but being insufficient, in the absence of the biodegradable polymeric material, to provide a stent capable of maintaining patency of a lumen upon implantation of the stent into the lumen.

2. (Original) The intraluminal stent of claim 1, wherein the metallic reinforcing component comprises a biocompatible metal selected from the group consisting of stainless steel, titanium alloys, tantalum alloys, nickel alloys, cobalt alloys and precious metals.

3. (Original) The intraluminal stent of claim 2, wherein the biocompatible metal comprises a shape memory alloy.

4. (Original) The intraluminal stent of claim 3, wherein the shape memory alloy comprises a nickel-titanium alloy.

5. (Original) The intraluminal stent of claim 1, wherein the biodegradable polymeric material comprises a biocompatible biodegradable polymer selected from the group consisting of polylactic acid, polyglycolic acid, polycaprolactone, polyorthoesters, and trimethylene carbonate polymers, as well as copolymers and mixtures thereof.

6. (Original) The intraluminal stent of claim 1, wherein the stent is selected from the group consisting of endovascular, biliary, tracheal, gastrointestinal, urethral, ureteral and esophageal stents.

7. (Previously presented) The intraluminal stent of claim 6, wherein the stent is selected from the group consisting of a balloon-expandable stent and a self-expandable stent.

8. (Previously presented) The intraluminal stent of claim 6, wherein the stent is an endovascular stent.

9. (Original) The intraluminal stent of claim 1, wherein the metallic reinforcing component comprises a plurality of apertures.

10. (Previously presented) The intraluminal stent of claim 9, wherein the metallic reinforcing component is selected from the group consisting of an open-mesh network comprising one or more knitted, woven or braided metallic filaments; an interconnected network of articulable segments; a coiled or helical structure comprising one or more metallic filaments; and a patterned tubular metallic sheet.

11. (Previously presented) The intraluminal stent of claim 9, wherein the metallic reinforcing component is selected from the group consisting of an open-mesh network comprising one or more knitted, woven or braided metallic filaments and a coiled or helical structure comprising one or more metallic filaments, and wherein said metallic filaments comprise two or more different metals.

12. (Previously presented) The intraluminal stent of claim 9, wherein the metallic reinforcing component is a patterned tubular metallic sheet and wherein the patterned tubular metallic sheet is formed by laser cutting or chemical etching of a metallic sheet.

13. (Original) The intraluminal stent of claim 9, wherein the biodegradable polymeric material covering at least a portion of the metallic reinforcing component comprises a biodegradable polymeric material coating layer.

14. (Previously presented) The intraluminal stent of claim 13, wherein said biodegradable polymeric material coating layer comprises one or more therapeutic agents, one or more diagnostic agents, or a combination of one or more therapeutic agents and one or more diagnostic agents.

15. (Original) The intraluminal stent of claim 9, wherein the biodegradable polymeric material covering at least a portion of the metallic reinforcing component comprises two or more biodegradable polymeric material coating layers.

16. (Previously presented) The intraluminal stent of claim 15, wherein one or more of the biodegradable polymeric material coating layers comprise one or more therapeutic agents, one or more diagnostic agents, or a combination of one or more therapeutic agents and one or more diagnostic agents.

17. (Previously presented) The intraluminal stent of claim 16, wherein different therapeutic agents or different combinations of therapeutic agents are present in two or more of said biodegradable polymeric material coating layers.

18. (Original) The intraluminal stent of claim 15, wherein at least two of said biodegradable polymeric material coating layers have different rates of biodegradation.

19. (Previously presented) The intraluminal stent of claim 16, wherein at least two of said biodegradable polymeric material coating layers comprise a therapeutic agent and have different rates of release of the therapeutic agent therefrom.

20. (Original) The intraluminal stent of claim 9, wherein the metallic reinforcing component and biodegradable polymeric material are provided within a laminated structure.

21. (Original) The intraluminal stent of claim 20, wherein the metallic reinforcing component is disposed between two or more layers of the biodegradable polymeric material.

22. (Original) The intraluminal stent of claim 21, wherein the two or more layers comprise different biodegradable polymeric materials.

23. (Previously presented) The intraluminal stent of claim 21, wherein at least one of said two or more layers comprises one or more therapeutic agents, one or more diagnostic agents, or a combination of one or more therapeutic agents and one or more diagnostic agents.

24. (Previously presented) The intraluminal stent of claim 23, wherein different therapeutic agents or different combinations of therapeutic agents are present in two or more of said layers.

25. (Original) The intraluminal stent of claim 21, wherein at least two of said layers have different rates of biodegradation.

26. (Previously presented) The intraluminal stent of claim 23, wherein at least two of said layers comprise a therapeutic agent and have different rates of release of the therapeutic agent therefrom.

27. (Original) The intraluminal stent of claim 1, wherein a surface of the metallic reinforcing component is passivated to enhance its biocompatibility.